K080049
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JAN 23 2008

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510(k) Summary

Submitted By

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Contact Person

Mark Wallace
Vice-President Quality

Date Prepared

December 27, 2007

Trade Name

VascuView Ultrasound System

Common Name

Ultrasonic Pulsed Echo Imaging System
Diagnostic Ultrasound Transducer

Classification Name

Ultrasonic Pulsed Echo Imaging System
FR Number: 892.1560
Product Code: 90-IYO

Diagnostic Ultrasound Transducer
FR Number: 892-1570
Product Code: 90-ITX

Legally-Marketed Equivalent Devices

Interson SR 7.5 MHz USB Ultrasound Probe System (k070907)

Sonosite iLook 25 Personal Imaging Tool (k021628)

Description of the Device

The VascuView ultrasound system provides ultrasound imaging of peripheral vascular structures in order to provide for ultrasound guidance for placement of needles and catheters in these structures. The VascuView system consists of the following components:

Ultrasound Probe and Cable. The handheld ultrasound probe is the Interson SR 7.5 MHz USB ultrasound probe (the same as the predicate device listed previously). The probe consists of a single-element mechanical sector scanner that contains the ultrasound pulser and receiver within the hand piece. It has a push button to activate scanning and capturing of images and video clips. The probe is connected to the pc via the included USB cable. The fundamental scan frequency (excitation frequency) is 7.5 MHz, allowing visualization of vessels at depths of 0.5 to 6.0 cm. The nose cone of the ultrasound probe is made of biocompatible material sufficient for its use (RT-18 TPX Polymethyl Pentene).

Tablet PC. A Kiosk tablet pc is provided which facilitates intuitive touch screen operation. The tablet pc is provided with a medical-grade power supply and medical-grade power cord. The pc provides a 5 vdc power supply to the ultrasound probe via the USB cable. The pc also provides for the operation of the software and storage of archived images and video clips.

VascuView Software. All features and controls of the system are provided for in the VascuView software which comes pre-loaded onto the tablet pc. The VascuView software uses an icon-based interface whereby the user can select any of the primary functional screens at any time by clicking on an icon located on the screen, for that function. The software enables ultrasound image capture and review, image controls for near, mid, and far gain, as well as image intensity and contrast, linear measurement calipers, image depth grid lines, zoom, display of needle guide lines, and printing.

Intended Use

The VascuView ultrasound system provides ultrasound imaging of peripheral vascular structures in order to provide for ultrasound guidance for placement of needles and catheters in these structures. The VascuView ultrasound system is not intended for fetal or ophthalmic applications.

The intended use of the VascuView system is slightly more limited than that of the Interson USB Ultrasound Probe System in that it's intended use does not include visualization of small organs (although that intended use was for the range of probes cleared under k070907). Likewise, the intended use of the VascuView system is also more limited than the Sonosite iLook 25, although the iLook 25 is marketed for vascular access.

Technological Characteristics Compared with Predicate Devices

The VascuView Ultrasound System utilizes the Interson model SR 7.5 MHz ultrasound probe, which was previously cleared under k070907 (formerly referred to as model number VC 7.5 MHz ultrasound probe – see Attachment 5A). The probe is indicated for use for peripheral vascular and small organ (intended for use in biopsy). The scope of the application for the VascuView has been limited to just peripheral vascular, primarily for assistance in vascular access (see Attachment 5B for transducer indication for use form). There are no differences or modifications made to the Interson probe.

The differences between the iLook 25 and the VascuView Ultrasound System include that the iLook is a dedicated device, while the VascuView system utilizes a tablet pc. This makes little difference in the actual use of the device since the VascuView is set up to launch immediately into the VascuView software. The VascuView does provide for a significantly larger screen, approximately 4 times greater in viewing area to aid in visualization. Additionally, while the iLook 25 is limited to storage capacity of 74 images, the VascuView system has virtually unlimited storage (tens of thousands of images on tablet pc hard drive and ability to connect external hard drives if additional storage is required).

The iLook 25 also provides a power Doppler mode that is intended indicate by different colors (red or blue) directionality of blood flow within vessels which, given the anatomical location of the vessel and orientation of the ultrasound probe, assists the user in determining whether the vessel is a vein or artery. This determination may also be made in either the iLook 25 or the VascuView system by observing whether the vessel is pulsing (indicating an artery) or not (indicating a vein), in addition to anatomical location.

The iLook 25 incorporates a linear array, while the VascuView system utilizes a single-element sector scan transducer. The linear array allows a deeper penetration by the iLook (deeper than that typically required for peripheral vascular), although a narrower profile. The sector scan sweep of the VascuView provides for a full 60° viewing angle at a depth of up to 6.0cm (sufficient for peripheral vascular). Therefore, the VascuView provides a greater field of view which combined with the larger monitor offers an enhanced resolution of scan.

The stated measurement accuracy of the iLook 25 is ±2% plus 1% full scale, while the VascuView has a slightly better measurement accuracy of ±2% plus 0.5% full scale.

Non-Clinical Performance Data

The VascuView has been tested and assessed as compliant with the requirements of several international safety standards, including IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, and IEC 60601-2-37 (including acoustic output limits), and others. Additionally, the measurement accuracy of the VascuView system was confirmed via a measurement validation test protocol using wire phantoms. The software has been also been validated using a test protocol.

Clinical Performance Data

None submitted.

Conclusions from Non-Clinical (and Clinical) Data

Based upon the results of the data as summarized above, the VascuView system has demonstrated that it is as safe, as effective, and performs as well as or better than the predicate devices. Furthermore, based on the comparison with the predicate devices as shown in the discussion above, as well as guidance provided by FDA 510(k) Substantial Equivalence Decision-Making Process Flowchart, the Escalon Vascular Access VascuView ultrasound system is deemed to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2008

Escalon Medical Corp.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street, N.W.
BUFFALO MN 55313

Re: K080049
Trade/Device Name: VU62000 VascuView Ultrasound System
Regulation Number: 21 CFR §892.1560
Regulatory Class: II
Procode: IYO
Dated: January 7, 2008
Received: January 8, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the Interson SR 7.5 MHz Mechanical Sector Probe intended for use with the VU62000 VascuView Ultrasound System, as described in your premarket notification.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions.

Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (240) 276-0120. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (240) 276-0100. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Ms. Lauren Hefner at (240) 276-3666.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Ultrasound Device Indication For Use

510(k) Number

Device Name VU62000 VascuView Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N								
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:_____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080049

Ultrasound Device Indication For Use

510(k) Number

Device Name Interson SR 7.5 MHz Mechanical Sector Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		P								Note 3
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P								Note 3
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: **Note 3: Includes imaging for guidance of biopsy (previously cleared under 510(k) 070907 – model no. VC 7.5 MHz)**

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
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